International Journal of Sciences: Basic and Applied Research (IJSBAR)

ISSN 2307-4531
(Print & Online)

https://gssrr.org/index.php/JournalOfBasicAndApplied/index

Research Design and Methods in Community Team Lifestyle Immersion Program for Chronic Disease Prevention and Control

Flora Ukoli[a]*, Jatheender Kumar[b], Chike Nzerue[c], Emmanuel Adediran[d], Dontal Johnson[e], Adrian Samuel[f], Stephania Miller-Hughes[g]

[a]*Professor, Department of surgery and PI for Community Team Lifestyle Immersion Program for control of chronic disease prevention and control Meharry Medical College Nashville, TN USA. 2025*

[b]*Postdoctoral fellow, Department of Surgery Meharry Medical College Nashville, TN, USA. 2025*

[a]*Email: fukoli@mmc.edu,* [b]*Email: jkuma766@mmc.edu ,* [c]*Email: cnzerue@mmc.edu*

[d]*Email: emmanueal.adediran@mmc.edu,* [e]*Email: djohnson@mmc.edu*

[f]*Email: dsamuels@mmc.edu,* [g]*Email: smiller@mmc.edu*

Abstract

Persisting disparities in the control of chronic diseases are linked to several barriers to health prevention, including cultural norms, insufficient attention to health education, lack of access to physical activity, large serving portions, and excess added sodium and sugar by the food industry and restaurants [1]. In line with lifestyle modifications proposed for several decades [2, 3, 4, 5], the goal of this study is to develop and evaluate the efficacy of a Lifestyle Immersion intervention for chronic disease control. The study will be conducted in two settings, the community and the health facility, thus addressing the individual, interpersonal, and organizational levels. This study introduces the team concept in health behavior modification. It will compare the effectiveness of interventions among participants in the study's intervention arm (Team Arm) and the control group (Individual Arm).

Received: 6/1/2025
Accepted: 7/16/2025
Published: 7/26/2025

---

* *Corresponding author.*

Participants will undergo a 6 month intervention adapted from the Centers for Disease Control and Prevention and the American Heart Association's recommendations for blood pressure control and cardiovascular health. Participants will receive education to increase relevant knowledge and training to develop the necessary skills, in addition to strategies for successfully adhering to LS7 and the DASH [6]. The primary study outcomes are systolic and diastolic blood pressure changes measured at enrollment and follow-up at 6 and 12 months. The secondary outcome measures include LS7 and DASH adherence scores at 6 and 12 months, as well as other pre-specified outcomes such as A1c, which assesses nutritional status at 6 and 12 months. The evidence for the effectiveness of lifestyle modification and the primary outcome of the study is controlling blood pressure through lifestyle modifications and promoting optimal health, particularly concerning African American populations [3, 10].

Keywords: Lifestyle Immersion; Blood pressure control; health behavior; community engagement.

1. Introduction

Persisting disparities in the control of chronic diseases are linked to several barriers to health prevention, including cultural norms, insufficient attention to health education, lack of access to physical activity, large serving portions, and excess added sodium and sugar by the food industry and restaurants [1]. In line with lifestyle modifications proposed for several decades [2, 3, 4, 5], the goal of this study is to develop and evaluate the efficacy of a Lifestyle Immersion intervention for chronic disease control. Participants will be invited into an active mental and practical process of involvement and commitment to lifestyle change that will benefit their health status. The study will be conducted in two settings, the community and the health facility, thus addressing the individual, interpersonal, and organizational levels. Most interventions target individual health behaviors and assess their impact on well-being. This study introduces the team concept in health behavior modification. It will compare the effectiveness of interventions among participants in the study's intervention arm (Team Arm) and the control group (Individual Arm). Participants will undergo a 6-month intervention adapted from the Centers for Disease Control and Prevention and the American Heart Association's recommendations for blood pressure control and cardiovascular health, which have been implemented in several clinical trials with impressive results. Participants will receive education to increase relevant knowledge and training to develop the necessary skills, in addition to strategies for successfully adhering to LS7 and the DASH [6]. The evidence for the effectiveness of lifestyle modification in controlling blood pressure and promoting optimal health is compelling [7, 8, 9], particularly concerning African American populations [3, 10].

African Americans may require additional motivational support to first accept the notion of change of lifestyle and to adhere to the changes that may be a major shift in their eating and exercise habits. The need to positively impact chronic disease, particularly hypertension, and morbidity in the African American population deserves both pharmaceutical and non-pharmaceutical approaches. With regards to changing physical activity behavior, motivational messages could be tailored to focus on Instrumental exercise goals. Exercising in a group can be more motivational. Motives that influence physical activity participation are critical for developing interventions to promote higher level of involvement [11]. The key to assisting hypertension individuals in acquiring good lifestyle behaviors is lifestyle adjustment [12]. Effective treatment and control techniques require a detailed

understanding of the consequences of smoking, drinking alcohol, and consuming unlimited salt. Lifestyle modification should be used to prevent mild hypertension and to reduce the dose levels of drugs needed to control hypertension.

This will be a randomized intervention developed using Community Engagement Research principles [13] and will be delivered in person, with some selected education sessions on the Zoom platform and Online modules. The project was approved by the Institutional Review Board (IRB) of Meharry Medical College (Reference # 25-02-1555). The funding authority is NIH. Project number: 5P50MD01347-04.

A brief evaluation survey will be completed by four physicians/cardiologists at the Meharry Medical College Clinics, who will not be involved in the study implementation. This document is to record their endorsement of the intervention, which will address all LS7 elements, including a DASH eating plan and a physical activity plan. The primary study outcomes are systolic and diastolic blood pressure changes measured at enrollment and follow-up at 6 and 12 months. The secondary outcome measures include LS7 and DASH adherence scores at 6 and 12 months, as well as other pre-specified outcomes such as A1c, which assesses nutritional status at 6 and 12 months. Other study biomarkers, such as urine sodium, A1C for diabetes, serum PAI-1 for hypertension, and IL-6 and CRP for obesity, will be assayed at Meharry Medical College research laboratories using fasting and random urine and blood samples collected at enrollment and follow-up. The intervention will be designed to provide participants with the knowledge, competence, and skills necessary to make lifestyle modifications that control hypertension and prevent adverse complications. The study community recruitment sites will be at five selected MDHA locations and health fairs, while the health facility recruitment sites will be at the Mathew Walker Comprehensive Health Center (MWCHC) and the Nashville General Hospital (NGH) Clinics at Meharry Medical College. The study's comparison groups will consist of participants who received the intervention to act independently versus those who will be assigned to participate in teams. Team participation is expected to provide additional motivation for lifestyle modifications to control chronic diseases.

2. Research Methods

Phase 1: Health Behavior Assessment.

Phase 2: Intervention Development.

Phase 3: a): Program Implementation.

b): Program Effectiveness Evaluation.

3.1 Phase 1: Health Behavior Assessment

LS7 and DASH Survey*:* A 2-page Likert style self-administered survey will be developed to assess the level of awareness, knowledge, and attitude about Life's Simple 7 and the DASH Eating Plan. A sample of 40 adults from MWCHC and NGH clinic waiting rooms will complete this survey to provide baseline information for the selection and development of education materials for this intervention.

3.2 Phase 2: Intervention Development

Physicians mention healthy lifestyle to their patients and offer useful brochures to improve their knowledge and skills about healthy living. This strategy works for some patients but may be too passive and therefore ineffective for others. It is usually not clear if all patients understand or read brochures collected from the doctor's office or other sources. This will be interactive intervention, an immersion, that will include oral presentations and practical demonstrations by lifestyle experts in the areas of nutrition, physical activity, body weight management, and blood pressure monitoring. The study protocol, intervention design, presentation drafts, consent and HIPAA forms, surveys, education materials, brochure, flyers, and participant incentive items and value will be reviewed and revised by a 12-Person CAB constituted of six lay adults, two physicians, two nurse practitioners, a dietician or nutritionist, an exercise trainer, and a community leader. Two 2-hour sessions, a week apart, will be convened to review and revise the content and delivery of the intervention.

4.1 Project Surveys, Presentations, Demonstrations, and other materials used in the project

1). Presentations (20 minutes each):

- Intervention Introduction: AHA Life's Simple 7 & The DASH Eating Plan.
- Team concept and team dynamics in lifestyle modification motivation.

Figure 1: Life simple 7 adapted from American Heart Association.

2). Demonstrations: (Video/Practical):

- Healthy Plate: Serving portions.
- Physical activity types and levels: Aerobics, Muscle Strength, and walking/jogging.
- Blood pressure/ Anthropometric measurement.

3). Research Tools:

- Demographics & Medical History; BP and Physical Measurements.
- Life's Simple 7 assessment survey.
- DASH eating plan assessment survey.
- Bio sample; Urine and blood collection protocols.

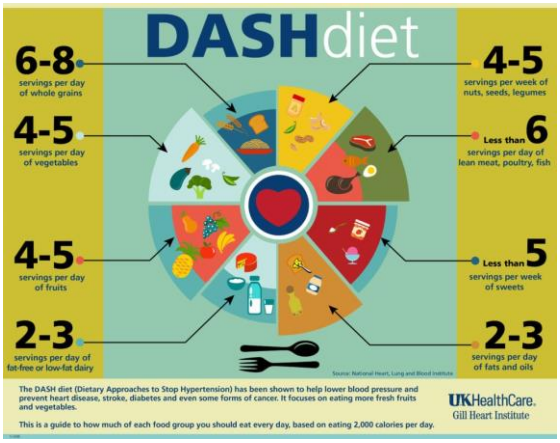

Figure 2: DASH diet adapted from the American Heart Association

4). Human Subject Safety and Protection materials:

Consent forms, HIPAA forms, Recruitment flyers, Posters.

5). Moderator Script for community engagement sessions: A guide for CAB discussion sessions.

6). Bio sample collection & handling: 5.0 ml serum/plasma will be collected by standard biosafety protocols. Samples will be stored as 250 ul aliquots at -80^{o}C to avoid freeze-thaw cycles. Biomarkers will be assayed using the human metabolic panel kits (Meso Scale Discovery, Rockville, MD, USA) and read on the MESO Quick Plex SQ 120MM (Meso Scale Discovery) located at the Molecular Biology Core Facility at Meharry Medical College.

4.2 Phase 3a: Program Implementation

We shall recruit 110 adults from the community and 110 MWCHC/NGH hypertension patients to complete the study surveys, baseline body-fat distribution measurements, medical history, and lifestyle surveys. Enrolled

participants will be randomized to a 'Team Arm' or 'Individual Arm' of the 6-month TLIP after signing consent. Teams will consist of 4 participants of diverse ages, gender and health status. Trained research staff will carry out research activities at the program partners sites (MDHA and MWCHC) with the assistance of assigned staff at that location.

4.3 Randomization Plan

Participants will be assigned a 3-digit study identification number (001 – 220) at enrollment. A random allocation sequence will be generated in blocks of 8, separately for each site. For study arm allocation, participants will select a colored disc (Blue-Team & Green-Individual) concealed in envelopes prepared by the PI (Ukoli F.) and given to the program coordinator (PC). The participant will open the selected envelope in the presence of the PC, and the PC will then place the participant in the study arm revealed. Participants, PI, and PC will not be blinded to the study arm assigned; however, the data collection and data entry research assistants (RAs) will be blinded as to study arm allocation.

4.4 MDHA Enrollment Plan

The study will be advertised in the MDHA newsletter, flyers will be placed in all mailboxes, a poster displayed in the common room, active in-person recruitment by the site RA, and by word-of-mouth.

4.5 MWCHC/Meharry Clinics Enrollment Plan

Patients diagnosed with hypertension in the last 3 years are identified from the clinic records, and new patients with hypertension will be invited to participate by their physician. Flyers will be distributed in the clinics and a poster will be displayed in the waiting area.

Table 1: Tentative TLIP Project timeline

Tentative TLIP Project Timeline in Quarters (Q) for 2½ Years												
Research Project Activities	Annual Quarters per Year											
	Y1: Oct. '23 - Sept. 24				Y2: Oct. 24 - Sept. 2025				Y3: Oct. 2025 - June 2026			
	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Development: CAB Sessions	X											0
Hire & Train Research Staff	X	X	X									0
Intervention/IRB Documents	X	X										0
IRB Application		X										0
Train MWCHC/MDHA partners	X	X	X									0
Trial Run: 2 Teams & 8 Individuals			X									0
TLIP Implementation: Pre-Intervention			X	X	X	X	X	X				0
TLIP Follow-Up					X	X	X	X	X			0
Data Analysis: Initial & continuing					X	X	X	X	X			0
Result Dissemination							X		X		X	0

4.6 Participant Responsibility

Eligible participants will read, have their questions answered, and sign the study Consent & HIPPA forms, after careful and detailed explanation by the PA/PC.

1). Pre-Intervention Survey: [1½ hours]

- Demographics, Medical History, Physical Measurements, BP Measurement.
- Life's Simple 7 Assessment Survey & DASH Eating Plan Assessment Survey.
- 5ml. urine & 5ml fasting blood samples will be collected.

2). Randomization Process:

Randomization in blocks of 8/site will be blinded. 8 people from each site, 4 assigned to 'Team Arm' and 4 assigned to 'Individual Arm' will then be invited to the 1st project session.

3). 1st In-Person Project Session: A 2-hour discussion session.

a). TLIP Project Introduction: The PI (Ukoli F) will describe the project and explain LS7 and DASH intervention elements. Information about available fitness and chronic disease management programs in Davidson and surrounding counties will be provided. (Ross Fitness center at Meharry, Hadley Park Recreation

Center, YMCA locations etc.). Participants will be asked to indicate the locations they already attend.

b). Team Concept: The concept of 'team' will be explained to mean a group of people who have decided to motivate each other for action. Team leadership, rules, and scheduling will be discussed and the idea of competition discouraged.

c). CDC Recommendations for Physical Activity & Nutrition will be discussed.

d). Identifying Primary Care Physician and regular doctor visits will be emphasized.

4). 2nd In-Person Session: A 2-hour Practical demonstration.

- A Healthy Plate: Serving portions of different foods. (Video/Practical)
- Physical activity types and levels: Aerobics, Muscle Strength, Walking. (Video/practical)
- Blood Pressure measurement & Physical anthropometric measurements.

5). 3rd Session: 1-week after Session 2. 15-Minute telephone call:

To respond to questions and concerns & Reinforce knowledge and skills.

6). 4th Session: 4-weeks after Session 2. 1-hour Motivational Interview:

- Blood Pressure Monitor will be given to the participants
- Group Education Session to maintain interest and motivate adherence.
- 8 participants per group session lead by dietician, trainer, and PI
- Complete baseline Block Food Frequency Questionnaire.

7). 5th Session: 3-Month Follow-Up: In-person: 45-Minutes.

- Complete all Surveys, Blood Pressure and Physical Measurements.

8). 6th Session: 6-Month Follow-Up: In-person: 1½-hour

- Complete all Surveys, Blood Pressure and Physical Measurements.
- Bio sample collection.
- Complete a BLOCK Food Frequency Questionnaire.

9) 7th Session: 12-Month Follow-Up: In person: 1½-hour

- Complete all Surveys, Blood Pressure and Physical Measurements.
- Bio sample collection.
- Complete a BLOCK Food Frequency Questionnaire.

5. Phase 3b: Program Effectiveness Evaluation

Follow-up surveys and measurements will be scheduled for 6- and 12-month post-enrollment.

Pre- and post-intervention differences in primary and secondary outcomes will be compared across study arms for recruitment sites, separately and combined, by statistical methods.

Post-Intervention Survey at 6-Month Follow-Up: [1 hour]

- Physical measurements, Blood pressure measurements.
- Life's Simple 7 Assessment Survey & DASH Eating Plan Assessment Survey.
- 5 ml urine & 5ml fasting blood samples will be collected.

Post-Intervention Survey at 12-Month Follow-Up: [1 hour]

- Physical Measurements, BP Measurement.
- Life's Simple 7 Assessment Survey & DASH Eating Plan Assessment Survey.
- 5 ml urine & 5ml fasting blood samples will be collected.

LS7 & DASH Score System

- Each item on LS7 will be scored 0 (poor), 1(intermediate), and 2 (ideal): Overall score range of 0 to 14.
- DASH will be scored similarly such that the overall score for the 8 elements will range from 0 to 16.

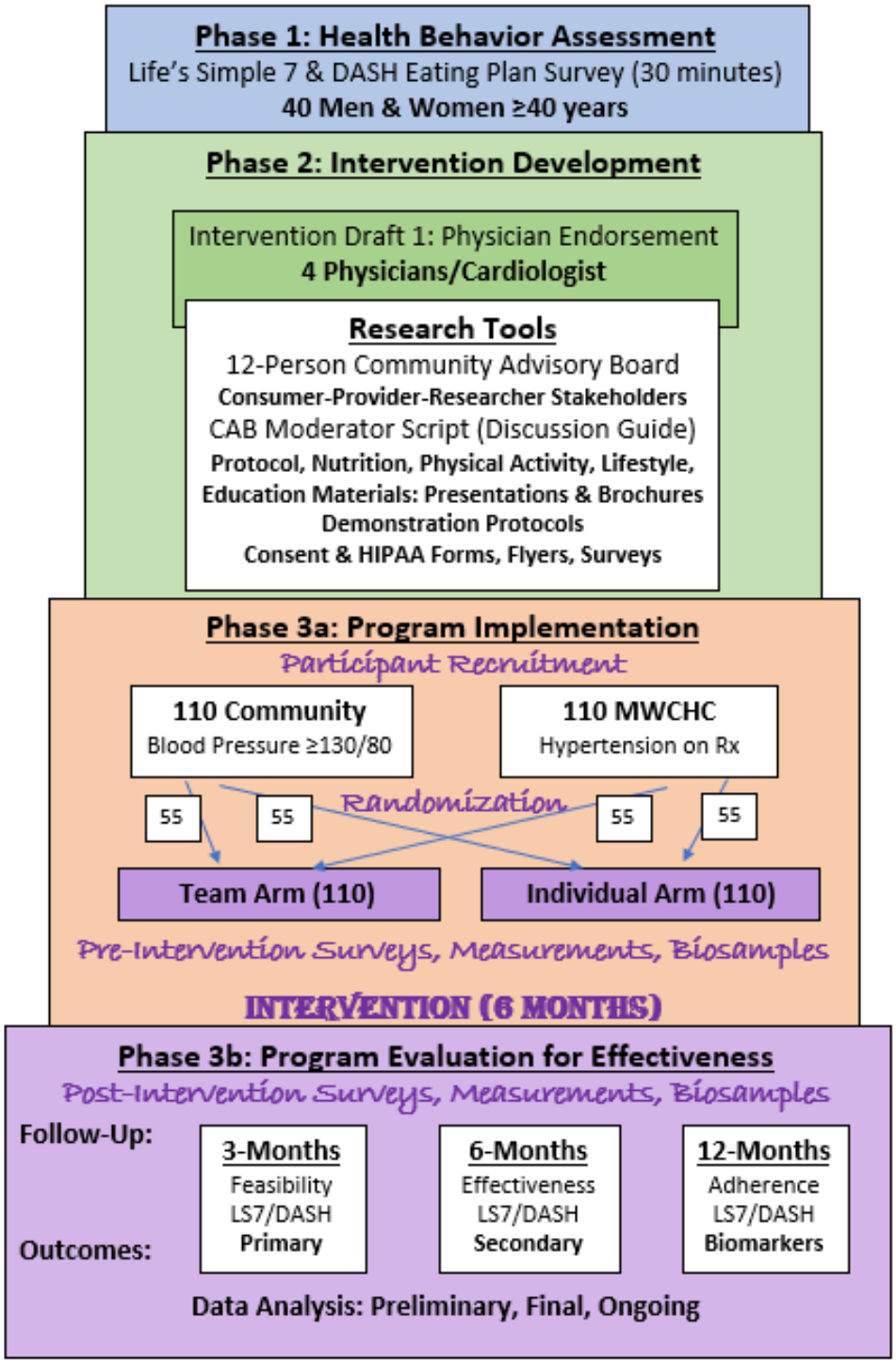

Figure 3: Team Lifestyle Immersion Program flow chart

6. Novel Concept and Approach

By using well tested research methods and evidence-based blood pressure control interventions, we propose a novel concept that will assign and encourage study participants to participate in Teams of 4 people. It is hoped that such participants will help each other to retain the knowledge and skills we show them, and that they will also motivate each other to adhere to the lifestyle modifications we shall introduce. Encouraging participants to plan at least 2 potluck dinners is another strategy to encourage home cooking and serving proper serving portions for an average 2,000 calorie diet.

7. Potential Difficulty

Maintaining study participation Teams will be a challenge especially if they do not live close to each other. This will be addressed by reinforcing the fact that one does not have to be at the exact same location as a team member, but to be involved in carrying out the said required activity.

8. Inclusion Criteria

Participants must reside in Davidson and surrounding counties of Tennessee, must be at least 30 years old, be at increased risk for developing hypertension (already diagnosed or a strong family history), be able to consent, and not planning to move from this study area in 12 months after enrollment.

9. Exclusion Criteria

Does not reside in Davidson and surrounding counties, is less than 30 years old, not at assessed increased risk for hypertension.

10. Sample Size Justification and Statistical Analysis Plan

Using a moderate effect size of 0.5, 51 subjects in each arm are needed to be able to reject the null hypothesis that there would be lower or equal retention in the mean diet and lifestyle seven scores among those that belonged to a team compared to those that did not belong to a team with 80% power. The type I error probability associated with this hypothesis is 0.05. The one-sided independent t-test was used. Assuming 25% attrition, a minimum sample of 68 participants per group, 136 total, will be needed. A sample size of 110 per group, 220 totals, will allow for additional sub-set comparisons to maintain the same power. G*Power software version 3.1.9.4 was used to perform the power analysis.

11. Data analysis plan

The primary study outcomes are systolic and diastolic blood pressure changes measured at enrollment and follow-up at 6 and 12 months. The secondary outcome measures include LS7 and DASH adherence scores at 6- and 12-months, as well as other pre-specified outcomes such as A1c, which assesses nutritional status at 6 and 12 months. Descriptive demographic statistics will be tabulated by study arm and study site. continuous

variables such as SBP, DBP, BMI, waist, and biomarker measures will be assessed for normality and log10 transformed as needed. All analysis will be performed on an intention-to-treat basis, and statistical tests will be performed two-sided using a 5% significance level. percent adherence (low, medium, high) for both LS7 and DASH, as well as patient healthy lifestyle knowledge, will be assessed between the study arms at 6- and 12-month follow-ups. The analysis will be based on the difference from baseline to follow-up, using matched t-tests and chi-square tests where appropriate. changes in LS7 and DASH scores will be measured using repeated measures ANOVA, followed by Tukey's post-hoc test. in the event the data is heteroscedastic, the non-parametric Friedman's test will be used in correspondence with the Games-Howell post-hoc test. The model will include terms for education, age, hypertension status, marital status, and employment, and secondary outcomes and biomarker measures will be used as an unstructured covariance matrix. All analyses will be performed in R/RStudio, SPSS, and SAS software (version 9.4; SAS Institute, Cary, NC).

References

[1]. P.K. Whelton, J. He, L. J. Appel, et. al. National High Blood Pressure Education Program Coordinating Committee. Primary prevention of hypertension: clinical and public health advisory from The National High Blood Pressure Education Program, "JAMA," Oct 2002 16;288(15):1882-8. PMID: 12377087 DOI: 10.1001/jama.288.15.1882

[2]. S G Sheps. Overview of JNC VI: new directions in the management of hypertension and cardiovascular risk. *"American Journal of Hypertension,"*1999 Aug;12(8 Pt 2):65S-72S. doi: 10.1016/s0895-7061(99)00111-9. PMID: 10478699

[3]. P. J. Elmer, R. Grimm Jr, B. Laing, et al. Lifestyle intervention: results of the Treatment of Mild Hypertension Study (TOMHS), " *Preview of Medicine*," Jul 1995;24(4):378-88. doi: 10.1006/pmed.1995.1062. PMID: 7479629

[4]. J. He, P. K. Whelton, L. J. Appel, J. Charleston, M. J. Klag. Long-term effects of weight loss and dietary sodium reduction on incidence of hypertension," *Journal of Hypertension*," 2000 Feb;35(2):544-9. PMID: 10679495 DOI: 10.1161/01.hyp.35.2.544

[5]. L. J. Appel, C. M. Champagne, D.W. Harsha, et.al. Writing Group of the premier Collaborative Research Group. Effects of comprehensive lifestyle modification on blood pressure control: main results of the PREMIER clinical trial *"JAMA,"* Apr 2003 ;289(16):2083-93.

[6]. F. M. Sacks, L. P. Svetkey, W. M. Vollmer, L. J. Appel, et. al. Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet. DASH-Sodium Collaborative Research Group, *"New England Journal of medicine*," Jan 2001. 4;344(1):3-10. PMID: 11136953 DOI: 10.1056/NEJM200101043440101

[7]. L. Chiavaroli, E. Viguiliouk, S. K. Nishi, et. al. DASH Dietary Pattern and Cardiometabolic Outcomes: An Umbrella Review of Systematic Reviews and Meta-Analyses. Nutrients. Feb 5, 2019 ;11(2):338.

doi: 10.3390/nu11020338.

[8]. V. A. F. Villalobos, R. Pedret, et. Al, "*Health Quality Life Outcomes*," Sep 14 2018 ;16(1):184. PMID: 30217193 PMCID: PMC6137925 DOI: 10.1186/s12955-018-1008-6

[9]. F. Najihah B. Allam, M. R. Ab Hamid, S. S. Buhari , H. M. Noor, "*Journal of Medicine Internet Research*," Mar 15 2021;23(3):e22465. PMID: 33720036 PMCID: PMC8074856 DOI: 10.2196/22465

[10]. B. W. Kong. Community-based hypertension control programs that work, " *Journal of Health Care Poor Underserved,"* Nov 1997 ;8(4):409-15. doi: 10.1353/hpu.2010.0031. PMID: 9334533

[11]. S. Mahmood, K.U. Shah, T. M. Khan et al. Non-pharmacological management of hypertension: in the light of current research," *International Journal of Medical Sciences*," 2019;188(2):437-452

[12]. K. Molanorouzi, S. Khoo, T. Morris. Motives for adult participation in physical activity: type of activity, age, and gender*," BMC Public Health,"* Jan 2015 31:15:66.

PMID: 25637384 PMCID: PMC4314738 DOI: 10.1186/s12889-015-1429-7

[13]. Y.A Joosten, T.L. Israel, N.A. Williams, et al. Community Engagement Studios: A structured approach to obtaining meaningful input from stakeholders to inform research. "Academy of medicine," 2015;90(12):1646-1650. PMID: 26107879 PMCID: PMC4654264 DOI: 10.1097/ACM.0000000000000794